This Page Is Inserted by IFW Operations and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.

PCT

DEMANDE INTERNATIONALE PUBLIEE EN VERTU DU TRAITE DE COOPERATION EN MATIERE DE BREVETS (PCT)

(51) Classification internationale des brevets 5:

(11) Numero de publication internationale:

WO 91/16018

A61F 2/44, A61B 17/60

(22) Date de dépôt international:

Al

(43) Date de publication internationale: 31 octobre 1991 (31.10.91)

(21) Numéro de la demande internationale:

PCT/FR90/00285

19 avril 1990 (19.04.90)

650620

(71)(72) Dépossats et laveatrers: BREARD, Francis, Henri [FR/FR]; 13, rue Friant, F-75014 Paris (FR), GRAF, Henry [FR/FR]; 12, quai Jules-Courmont, F-69002 Lyon (FR).

(74) Mandataire: CABINET MALEMONT; 42, avenue du Président-Wilson, F-75116 Paris (FR).

(81) Etats désignés: AU, JP, SU.

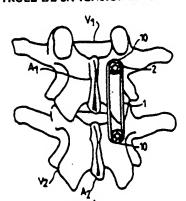
Peblice

Avec rapport de recherche internationale.

SUPPLE

(54) Title: PLEXIBLE INTERVERTEBRAL STABILIZER, AND METHOD AND APPARATUS FOR DETERMINING OR CONTROLLING ITS TENSION BEFORE IT IS PLACED ON THE BACK BONE

(54) Titre: STABILISATEUR INTER-VERTEBRAL SOUPLE AINSI QUE PROCEDE APPAREILLAGE POUR LA DE-TERMINATION OU LE CONTROLE DE SA TENSION AVANT MISE EN PLACE SUR LE RACHIS



(57) Abstract

An intervertebral stabilizer comprising one or more flenible ligament(s) (1, 1a, 1b), each of which has a device for hooking onto two respective vertebrae and/or is linked to two securing elements (2, 3) such as screws (2, 3) with free heads (4) which can be implanted in respective vertebrae (V1, V2). A method and an apparatus for determining or controlling the tension in an intervetebral stabiliser before it is placed on the backbone are also described. The method, which is carried out after the implantation in each of said vertebrae (V1, V2) of a respective rigid rod extending outside the patient's body, involves, for each pair of neighbouring rods, immobilizing both said rods in an initial position and, if the pain to be eliminated by said stabilizer persists, altering the distance between said rods. Then, said rods are immobilized in their new positions and a new pain test is carried out. These operations may be repeated until said pain disappears, and the correct length of the ligament is deduced from the final distance between said rods.

(57) Abrège La plesente invention concerne un stabilisateur inter-vertebral qui comprend un ou plusieurs ligament(s) souple(s) (1, 1a, 1b) chacun muni de inovens d'accrochage a deux vertebres respectives et 'ou associe(s) a deux organes de retenue (2, 3), tels que des vis (2, 3) à tête libre (4) implantables chacune dans une vertebre respective (V₁, V₂). La presente invention a également pour objet un procédé, et l'appareillage associé, pour déterminer ou contrôler la tension d'un tel stabilisateur intervertèbral avant sa mise en place sur le rachis. Ce procédé, mis en œuvre après implantation dans chacune des vertèbres concernées (V₁, V₂), d'uné tige rigide respective se prolongeant hors du corps du patient, consiste, pour chaque paire de tiges voisines, à immobiliser les deux tiges dans une position initiale et, en cas de persistance de la douleur dont la cause doit être supprimée par le stabilisateur, à modifier la distance entre les tiges, puis à immobiliser ces dernières dans leur nouvelle position relative et à effectuer à nouveau le test de douleur, ce cycle d'operations étant éventuellement repêté jusqu'à ce que ladite douleur disparaisse, la longueur à donner au ligament étant déduite de la distance alors atteinte entre les deux tiges.

UNIQUEMENT A TITRE D'INFORMATION

Codes utilisés pour identifier les Etats parties au PCT, sur les pages de couverture des brochures publiant des demandes internationales en vertu du PCT

AT	Autriche	FI	Finlance	ML	Malı
AU	Australes	73	France	MN	Mangota
88	Barbaux	GA	Gaten	ME	Mauritanie
38	Balgune	C8	Revount-Uni	MW	Malewi
AF	Burking Fino	GN	Guende	NL	Pays-Bas
BG	Bulgarie	CA	Griss	MO	Nervase
N	Bánin	HU	Honers	PL	Polegne
BR	Bremi	r T	Italia	RO	Noumanii:
CA	Canada	JP.	Jagon	SD	Seulan
CF	Hépublana Centraficaine	KP	République populaire democratique	SE	Su dicio
CC	Congo		du Carte	SM	Sénégai
CH	Sweete	KR	République de Coree	SU	Union sovietius
CI	Côte d'Ivoire	u	Linchardmann	TD	Tehau
CM	Camproun	Lak.	Sri Lanka	TC	Togo
D€	Allemagne	LU	Lusembourg	US	Elate-Unio d'American
DK	Dengmark	MC	Manue		
ES	Espagnic	MC	Madagascar		•

Supple intervertebral stabiliser as well as process and apparatus for determining or verifying its tension before installation on the spinal column.

5

The present invention relates to an intervertebral stabiliser to be installed between at least between two vertebraes to correct defects in the spinal column.

Throughout the specification and claims, the words supple and flexible are utilised, however, different meanings are accorded to these two words. The word "supple" is related to objects that can change shape according to forces in all directions and keep that shape until other forces are applied: they can be easily folded and unfolded without breaking or damaging. The word "flexible" on the other hand is related to objects that can change their shape according to certain directions, however, will return to their initial position. They can be curved but can't fold and unfold.

Inter-vertebral stabilisers currently used to attenuate the often painful effects of diseases of the spinal column, such as scolioses, nucleus pulposus herniations or lumbar instabilities, take the form of metal plates or rods that are fixed to the vertebrae or to their spines, along the affected section of the spinal column, which has the drawback of completely immobilizing the vertebrae, hence of restricting or even completely preventing flexional or torsional movements of the patient's trunk.

The present invention has for its objective the provision of an intervertebral stabiliser either implanted or capable of being implanted which will overcome the aforementioned difficulties.

In preferred aspects the present invention also aims at providing a process for determining or verifying tension of such inter-vertebral stabilisers according to the present invention and providing apparatus for carrying out these processes.

10

5

10

15

次面次入

Accordingly, the present invention provides an inter-vertebral stabiliser adapted to be installed between at least two successive vertebrae comprising one or more supple ligaments and two retaining elements, each said retaining element having a free head for fastening a said ligament thereto, and each said ligament being provided with fastening means for fastening it to a respective one of said retaining elements whereby, in use, said retaining elements are implanted into a respective said vertebrae and at least one said ligament is fastened to said retaining elements.

10

5

According to a further aspect, the present invention provides an intervertebral stabiliser installed between at least two successive vertebrae, characterised in that it comprises one or more supple ligaments, each said ligament being provided with fastening means fastening the ligament between said two vertebrae with two retaining elements, each of the two retaining elements being implanted in a respective one of said vertebrae. In accordance with a still further aspect, the present invention provides an inter-vertebral stabiliser when installed between at least two successive vertebrae, said stabiliser comprising one or more supple ligaments, each ligament being provided with means for fastening it to the two respective vertebrae.

20

15

Advantageously, the or at least one supple ligament has the general form of a closed loop or, alternatively, is provided with a ring or a closed loop at each end thereof, whereby the ends of each ligament constitute said fastening means through which said ligament can be fastened by hanging to a spine or any other protrusion of a respective vertebra. When retaining elements are provided, each of them, being preferably a screw, is advantageously formed with a free head for fastening a respective end of the corresponding ligament.

...25

There is thus obtained a supple or semi-elastic inter-vertebral stabiliser which, according to its mode of implantation, on one side only or on both sides of the spines of the vertebrae concerned, on the front face or the rear face thereof, with a single ligament or with several ligaments chained together or even crossed with each other, makes it possible to compensate for all sorts of defects

30



or deformations of the spinal column by permitting sufficient clearance between the vertebrae not to hinder the patient in the flexional or torsional movements of his trunk.

5

Apart from this main advantage, the inter-vertebral stabilizer according to the invention is extremely simple to install: it suffices to engage the end of each ligament around for example two vertebral spines or two screws pre-implanted in the vertebrae.

5

10

15

20

25

30

To prevent any slipping of the ligament once it has been put in place, in the case where retaining elements, such as screws, are used, provisions is also advantageously made for fitting onto each retaining element, a removable cap that is radially over-dimensioned in relation to the head of the retaining element. The same effect can be obtained by alternatively providing the head of each retaining element with a lateral projection for retaining the ligament.

Before putting the stabilizer in place on the spinal column, its tension, i.e. the length at rest of the, or of each, stomble ligament, will naturally have to be determined precisely in accordance with the seriousness of the defect to be corrected and, for this purpose, the present invention proposes a process implemented after implanting, in each of the vertebrae concerned and at the point at which the corresponding ligament is to be fixed, a corresponding rigid rod extending out of the patient's body, this process being characterized in that it consists, for each pair of adjacent rods, in immobilizing the two rods at a predetermined distance from one another and, in the event of persistence, after a given time period has elapsed, of the pain the cause of which the stabilizer is intended to remove, in modifying the distance between the rods by a certain pitch and then immobilizing them in their new relative positions and carrying out the pain test once again, this cycle of operations being repeated, if necessary, until the said pain disappears, the length at rest to be given to the ligament then being deduced from the value of the distance then reached between the two rods.

This process can also be implemented for verifying and modifying the tension of one or more ligaments already in place on the spinal column, when the patient experiences pain after a less or more long period of use.

Another object of the invention is to provide an apparatus for determining

the tension of an inter-vertebral stabilizer according to the invention before it is put into place on the spinil column, the said apparatus being characterized in that it comprises a set of at least two rods each having an end for implantation in the corresponding vertebra, these rods being associated at least with a rigid link of adjustable length designed to join them together at a point remote from their implantation ends.

According to a preferred embodiment, the implantation end of each rod is constituted by an element having a head onto which is removably fitted an extension piece forming the remaining portion of the rod, designed to receive the rigid length-adjustable link.

Once the operation of determining the tension of the inter-vertebral stabilizer has been completed, the end elements of the rods, which will preferably be screws, can be advantageously held in place in the vertebrae to form the ligament retaining elements, and the ligament, after being produced to the length calculated using the process according to the invention, can easily be engaged around the said screws by sliding along the extension pieces before they are removed.

The rigid length-adjustable link can, for its part, take various forms, the simplest being that of a thin bar and two collars that can be fitted respectively onto the two rods and are provided with means for slidably supporting the bar between them, a bar locking member being provided on each collar.

Advantageously, the apparatus according to the invention further comprises an instrument for determining the length at rest of the ligament, which is formed by two crossed legs articulated on one another at their middle, the ends of the legs located on the same side of the articulation each having a substantially semi-circular contacting portion, which is applied onto the head of the corresponding retaining element. In this way, it is possible to determine between the other ends of the two legs of this instrument the length required for the ligament to be implanted, which can be measured using a graduated rule.

Embodiments of the inter-vertebral stabilizer according to the invention, together with a process and an apparatus for d termining their tension, will now be described in greater detail, but non limitatively, with reference to the accompanying drawings, wh rein:

10

5

l0

.5

:0

:5

- figure 1 shows a side view in partial cross-section of the inter-vertebral stabilizer according to the first embodiment of the invention;
- figure 2 is a front view of an inter-vertebral stabilizer according to the second embodiment of the invention;
- figures 2a and 2b show alternative embodiments of the stabilizer of figure 2;
- figures 3a, 3b and 3c illustrate one of the ligament retaining elements of the stabilizer of figure 1;
- figures 4a and 4b show, in longitudinal cross-sectional view and in front view respectively, one of the ligament retaining elements of the stabilizer of figure 2;
- figure 5 is a side view, in partial cross-section, of the apparatus according to the invention, represented in use on two adjacent vertebrae;
 - figure 6 is a cross-sectional view along line VI-VI of figure 5;
- figure 7 illustrates, in its position of use, a supplementary accessory of this apparatus, designed to determine the length at rest of the ligament; and
- figure 8 represents the apparatus of figure 5 as used for the insertion of the figure 1 igament around the retaining elements.

Figure 1 represents two adjacent vertebrae, V1, V2, of a patient's spinal column, linked by an inter-vertebral stabilizer according to the invention, which supple is corposed of a signal ligament 1 in the form of a closed loop and of two screws 2,3 each implanted in a corresponding vertebra to retain ligament 1 between them, said ligament being simply engaged around the widened cylindrical heads 4 of the screws, emerging from the vertebrae. Ligament 1 is an artificial supple ligament made of "Dacron" (registered trade-mark) or of any other plastics material, beautiful trade-mark) or of any other plastics material.

As more clearly shown in the longitudinal cross-sectional and front views of figures 3b and 3c, the head 4 of each screw comprises an axial blind hole 5 having a hexagonal cross-section, in which a hexagonal key can be engaged in order to implant the screw in the corresponding vertebra.

After ligament 1 has been put into place around the screws thus implanted, hole 5 of each of said screws is closed using a flat circular cap or plug 6, shown alone in figure 3a, said cap, the diameter of which is substantially

(A)

5

0

5

0

5

0

larger than that of head 4 of the screw, being screwed by means of a central pin 7 with a threaded end into a threaded bore 8 opening in the bottom of hole 5. To accomplish this screwing operation, use is made of a special key cooperating with two slots, 9,9a, formed on the periphery of each cap 6. Alternatively, each cap may be provided with a central hexagonal bore and screwed on the head 4 of the corresponding screw by using a hexagonal key engaged in this bor. By projecting radially right around the corresponding heads 4 of the screws, the two caps 6 preclude any likelihood of ligament 1 slipping off the said heads, as illustrated in figure 1.

5

.0 -

.5

10

25

30

The caps 6 are particularly useful when the inter-vertebral stabilizer Supple according to the invention comprises several supplementary flexible ligaments, such as illustrated at 1a and 1b in figure 1, chained together with first ligament 1, on the vertebrae preceding and following the two designated by V1,V2, with the help of the same number of supplementary retaining screws.

In the case illustrated in figure 2, in which only one ligament 1 in the form of a closed loop will have to be interposed between only two successive vertebrae V1,V2, the head 4 of each screw 2 or 3 can be provided alternatively with a lateral projection 10 of suitable height, as represented in profile and in front view in figures 4a and 4b. In this case, it will be necessary first of all to implant the two scraws 2,3 by orientating their projections 10 opposite one another so that ligament 1 can be then slid without any impediment around their heads 4, after which the screws will be given an additional half-turn to place projections 10 in their ligament retaining positions, as shown in figure 2.

The inter-vertebral stabilizer according to the invention makes it possible, according to its positioning, to combat numerous painful diseases affecting the spinal column. The stabilizer shown in figures 1 and 2 is put into place on the rear face of vertebrae V1,V2 and on one side only of their spines A1,A2. However, depending on the type of disease to be treated, it is possible to use two stabilizers according to the invention, mounted on either side of vertebral spines A1,A2 or crossed between the two vertebrae V1,V2, on the front or rear face thereof. In all cases, however, it is necessary to determine the t nsion of the stabilizer, i.e. the length at rest of its ligament 1, accurately before it is installed, as a function of the seriousness of the defect to be corrected.

For this purpose, the present invention proposes a process and an appar us for its implementation, which will now be described with reference to figures 5 to 8.

5

10

15

20

15

30

As it can be seen, the basic accessories of this apparatus are two rigid rectilinear rods, 11,12, which are fixed in the respective vertebrae V1,V2 by their ends which, in the preferred embodiment represented in figure 5, are formed by screws 2,3 of what is to become the stabilizer. Each screw is implanted in the way described above after a local surgical incision has been made in the patient's back in front of each vertebra for uncovering it. Each rod 11,12 is completed by a cylindrical extension piece 13 naving a threaded end 14, which is fitted onto the head 4 of the corresponding screw by screwing into its threaded bore 8 after removal of cap 6. For this purpose, the free opposite end of each extension piece 13 is provided with a hexagonal head 23 suitable for receiving a tightening key. It will also be noted that each extension piece 13 has a loot 13a which flares progressively until its diameter is substantially equal to that of the head of screw 4 onto which it is fitted.

The two rods 11,12 being thus implanted so as to extend out from the patient's back D, they are joined in the vicinity of their free ends 14 by crigid link 15 cf adjustable length and, by means of the latter, the distance between the rods is adjusted to a value that is predetermined as a function of the nature and the seriousness, previously diagnosed, of the defect to be corrected on the spinal column.

After the two rods have been thus immobilized in this initial position, the incisions in the patient's back are closed up and the patient is made to undergo a test which consists in verifying whether, at the end of a given period, possibly one to two days, the patient still experiences pain in the affected area of the spinal column. If this is the case, the spacing between rods 11,12 is slightly modified, generally for bringing them closer to one another (compression), by acting on the length of link 15, and the pain test is repeated over substantially the same period of time as before.

This dual operation will be repeated if necessary, preferably with a constant pitch of change in the spacing of rods 11, 12, until the patient no longer experiences any pain in the back. Once this result has been achieved, the length

at rest required for the ligament to be implanted between the vertebran is measured or calculated with maximum accuracy.

In practice, the maximum number of successive cycles of verifying operations leading to the elimination of pain will be three and, if the pain proves to persist after these three cycles of operations, this will mean that the defect that causes it is not present in the pair of vertebrae tested and the process according to the invention will then have to be applied to the following pair of vertebras or successively on the following pair(s) of vertebrae, until the pain disappears.

Of course, when several therithe ligaments are to be chained together, such as 1, la and 1b (figure 1), over a long section of the spinal column, the above described process will be applied simultaneously to all the successive vertebrae to be treated, using as many rods 11,12 as there are vertebrae and joining them two by two using length adjustable links such as 15.

5

5

This link, which is more clearly represented in figure 6, is in fact formed here by a thin cylindrical bar 16 retained on two collars 17,18, each of which is fixed to a corresponding rod 11, 12 by means of a lock screw 19. Bar 16 is more precisely housed so as to be able to slide freely in a groove 20 of each of collars 17,18 and is locked therein, after the spacing of the rods has been adjusted, by head 21 of lock screw 19 of the corresponding collar. Alternatively, of course, link 15 can take the form of a device with threaded rods with reversed screw pitches, which could even be fitted with a system for directly measuring the spacing between rods 11,12.

The length to be allocated to the ligament can be derived, by a trigonometrical calculation, from the distance d measured, for exampl near link 15, between rods 11,12 immobilized in the right position. According to an additional feature of the invention, however, it is possible, as an alternative, to measure directly the length to be allocated to ligament 1 between heads 4 of screws 2,3 by using an instrument which will now be described, together with its mode of use, with reference to figure 7.

As it can be seen, this instrument 24 for determining the length of the ligament takes the general form of a "pair of scissors" and is more specifically, formed by two legs, 25,26, of the same length, which cross in their middle and

are articulated on one another at their point of crossing by means of a lock screw 30. On the same side of this articulation 30, the ends of the two legs 25,26 carry a contacting piece, 28 or 29, which is substantially semi-circular and has a inner diameter slightly greater than that of the heads 4 of retaining screws 2,3. These contacting pieces 28 and 29 are facing each other and their inner arcuate face in flush with the inner side of the corresponding leg 25 or 26 of instrument 24. At their opposite ends, legs 25,26 are each provided with a ring, 31,32, to accommodate a finger.

5

10

15

30

.5

0

To measure the length of the ligament using the said instrument 24, an incision is first made in the patient's back as far as vertebrae V1, V2 are uncovered. Then, after having loosened screw 30 and by holding instrument 24 in one hand by means of rings 31,32, each of contacting pieces 28 or 29 is placed on a respective rod 11 or 12 and the instrument is caused to slide along these rods until the contacting pieces are bearing on the ends of heads 4 of screws 2,3. Screw 30 is then re-tightened and, using a graduated rule 33, the distance between the free ends 25a, 26a of legs 25,26 of instrument 24 is measured and the value of the length required for the ligament to be implanted between retaining screws 2,3 is thus obtained directly.

After this length measurement, ligament 1 or each of ligaments 1, 1a, 1b to be implanted is prepared from a tubular artificial ligament which is flattened and sewn back on itself. After link 15 has been removed, the ligament thus formed into a op is passed around the two extension pieces 13 and slid along them up to screws 2,3, around the heads 4 of which it is then engaged with the help, if necessary, of a special semi-cylindrically shaped tool 22, as shown in figure 8. Extension pieces 13 are then removed, caps 6 are screwed onto the heads of screws 2,3 (figure 1) or the latter are or entated in such a way as to place their projections 10 in ligament retaining position (figure 2); then the incisions in the patient's back is definitively closed up.

It goes without saying that numerous modifications can be made in the int r-vertebral stabilizer and in the apparatus that have just been described.

For instance, according to an alternative embodiment, shown on figure 2a, of the stabilizer of Figur 2, the ligament 1c is in the form of a single segment 40 to each ind of which a metallic ring 41 or 42 is attached, with which the ligament can be fastened by hanging over the head 4 of a respective retaining screw 2 or 1.

According to another alternative embodiment shown on figure 2b, the ligament 1d of the stabilizer, having the form of a closed loop, is passed through himself for defining a first end loop 43 which is engaged around the spine λ_1 of a respective vertebra V_1 . At its second end, the ligament 1d is placed around spine λ_2 of the lower vertebra V_2 , then re-passed through himself for forming a second end loop 45 after insertion of a locking pin 44. Spines λ_1 and λ_2 here play the role of the retaining screws 2,3, but it goes without saying that ligament 1d of figure 2b can also be associated with such screws, as those 1 and 1c of figures 2 and 2a. Inversely, ligaments 1 and 1c of figures 2 and 2a can be fastened by an hanging connection directly over spines λ_1 and λ_2 of vertebrae V_1 and V_2 , without the use of retaining screws, as the ligament 1d of figure 2b. Of course, a chained arrangement of a plurality of ligaments, as the one shown on figure 1, may also be obtained with the embodiments of figures 2a and 2b, by means of pre-implanted retaining screws or by direct fastening over the spines of the vertebrae concerned.

For their part, screws 2,3 could be replaced by any other retaining element capable of being implanted in a vertebra and provided with a free head for fastening a ligament end thereover.

Purthermore, rods 11, 12 of the apparatus of the present invention can be made in a single piece, the two-piece form of embodiment described above being preferable, however, when ligament retaining elements, such as screws, are used because, in this case, it precludes the need to reimplant said retaining elements after the preliminary operation for determining the tension of the stabilizer.

It should further be pointed out that the screws or other retaining elements 2,3, their caps 6 and rods 11,12 will preferably be made from a bio-compatible metallic alloy.



5

10

15

20

25

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS.

- 1. An inter-vertebral stabiliser adapted to be installed between at least two successive vertebrae comprising one or more supple ligaments and two retaining elements, each said retaining element having a free head for fastening a said ligament thereto, and each said ligament being provided with fastening means for fastening it to a respective one of said retaining elements whereby, in use, said retaining elements are implanted into a respective said vertebrae and at least one said ligament is fastened to said retaining elements.
- 2. An inter-vertebral stabiliser installed between at least two successive vertebrae, characterised in that it comprises one or more supple ligaments, each said ligament being provided with fastening means fastening the ligament between said two vertebrae with two retaining elements, each of the two retaining elements being implanted in a respective one of said vertebrae.
- 3. The inter-vertebral stabiliser according to claim 1 or claim 2, characterised in that the or at least one supple ligament has the general form of a closed loop, the ends of which constitute said fastening means.
- 4. The inter-vertebral stabiliser according to claim 1 or claim 2, characterised in that the or at least one supple ligament is provided, at each end thereof, with a ring or a closed loop constituting said fastening means.
- 5. The inter-vertebral stabiliser according to claim 1, characterised in that each of the retaining elements is provided with a removable cap, radially over-dimensioned in relation to the head of the retaining element, on which it can be fitted.
- 6. The inter-vertebral stabiliser according to claim 1, characterised in that the head of each retaining element is provided with a lateral projection for retaining the ligament.



- 7. An inter-vertebral stabiliser when installed between at least two successive vertebrae, said stabiliser comprising one or more supple ligaments, each ligament being provided with means for fastening it to the two respective vertebrae.
- 8. Process for determining or verifying the tension of an inter-vertebral stabiliser according to any one of claims 1 to 7, before its installation on the spinal column, this process, which is implemented after the implantation, in each of the vertebrae concerned and at the point at which the corresponding ligament is to be fixed, of a corresponding rigid rod extending out of the patient's body, being characterised in that it consists, in the case of each pair of adjacent rods, in immobilising the two rods at a predetermined distance from one another and, in the event where the pain, the cause of which is to be removed by the stabiliser, is persisting after a given time period has elapsed, in modifying the distance between the rods by a certain pitch, and then in immobilising the latter in their new relative positions and in carrying out the pain test once again, this cycle of operations being repeated, if necessary, until the said pain disappears, the length at rest to be given to the ligament then being deduced from the value of the distance then attained between the two rods.
- 9. Apparatus for implementing the process according to claim 8, for determining or verifying the tension of an inter-vertebral stabiliser according to one of claims 1 to 8, before it is put into place on the spinal column, characterised in that it comprises a set of at least two rods each having an end for implanting in the respective vertebra, the said rods being associated with at least one ngid link of adjustable length designed to join them at a point remote from their implantation ends.
- 10. The apparatus according to claim 9, characterised in that the implantation end of each rod is constituted by the corresponding retaining element of the ligament of the said stabiliser and each of the rods is completed by a removable extension piece fitting onto the head of said retaining element.



- 11. The apparatus according to claim 10, characterised in that the said length-adjustable rigid link comprises a thin bar and two collars that can be fitted respectively on the two rods and are provided with means for supporting the bar slidingly between them, an element for locking the bar being provided on each collar.
- 12. The apparatus according to any one of claims 9 to 11, characterised in that it comprises an instrument for determining the length at rest of the ligament, which is formed by two crossed legs articulated on one another at their middle, the ends of the legs located on the same side of the articulation each having a substantially semi-circular contacting portion.

DATED this 2nd day of May, 1994

FRANCIS HENRI BREARD and HENRY GRAF

WATERMARK PATENT & TRADEMARK ATTORNEYS THE ATRIUM 290 BURWOOD ROAD HAWTHORN VICTORIA 3122 AUSTRALIA

SKP/RJD/BB] (Doc. 33) AU5551890.WPC

TITLE:

Supple Plantber | Inter-vertebral atabilizer together with process and apparatus for determining its tension before installation on the spinal column

5

ABSTRACT OF THE DISCLOSURE

10

The present invention relater to an inter-vertebral stabilizer comprising supple one or more thanks ligaments (1,1a,1b), each of them being provided with means for fastening it to two respective vertebrae and/or associated with two retaining elements (2,3), such as screws, each of which is suitable for being implanted in a respective vertebra (V1,V2).

15

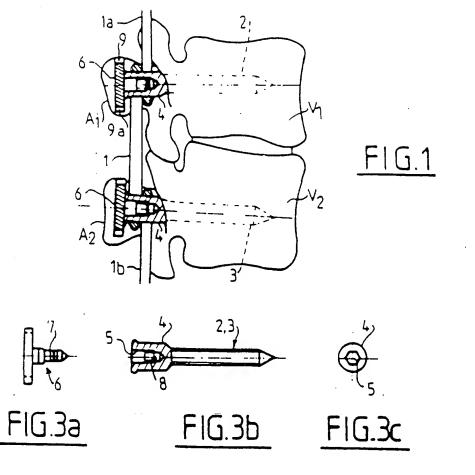
20

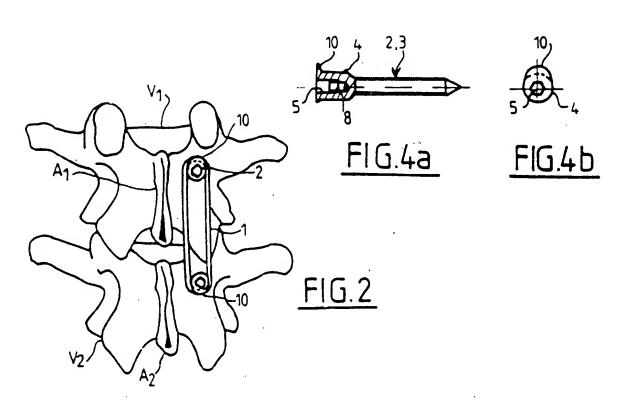
25

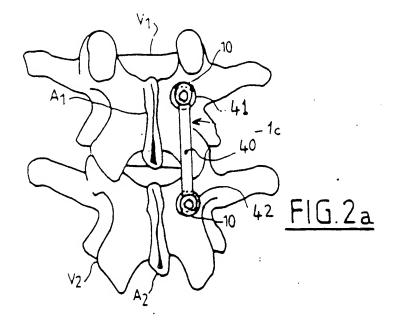
The present invention also relates to a process, and the associated apparatus, for determining or verifying the tension of such an inter-vertebral stabiliser before it is put into place on the spinal column. This process consists in implanting, in each of the vertebrae concerned (V1,V2), a corresponding rigid rod extending outside the patient's body and, in each pair of adjacent rods, in immobilizing the two rods in an initial position and, in the event where the pain, the cause of which is to be removed by the stabilizer, is persisting, in modifying the distance between the rods, then in immobilizing the latter in their new relative positions and in repeating the pain test, this cycle of operations being repeated, if necessary, until the said pain disappears, the length to be allocated to the ligament being deduced from the distance then attained between the two rods.

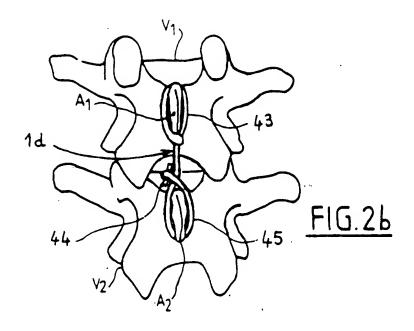
(FIGURE 1)

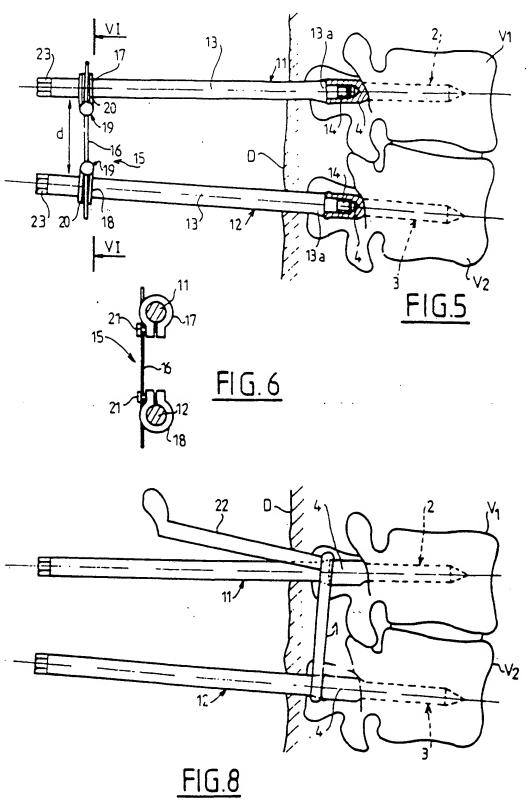


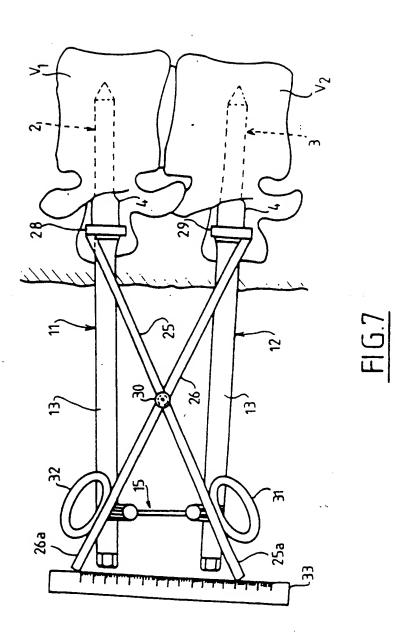












INTERNATIONAL SEARCH REPORT

International Application No PCT/FR 90/00285

I. CLASSIFICATI N F SUBJECT MATTER (il several classificati	ion symbols apply, indicate all) *	
According to International Patent Classification (IPC) or to both National	Classification and IPC	
Int.Cl. A 61 F 2/44, A 61 B 17/60		
II. FIELDS SEARCHED Minimum Documentati	on Searched 7	
	ssification Symbols	
Int.Cl. ⁵ A 61 F, A 61 B		
Documentation Searched other than to the Extent that such Documents are	n Minimum Occumentation e Included in the Fields Searched *	
III. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category * Chation of Document, 11 with Indication, where approx	priate, of the relevant passages 12	Relevant to Claim No. 13
X US, A, 4743260 (BURTON) 10 May 1988 see the whole document		1-5
Y		7–10
Y FR, A, 2275679 (CROCK et al.) 16 January 1976 see page 4, lines 18-35; figure	s 4-6	7-10
X EP, A, 0140790 (PEZE) 8 May 1985 see abstract; figure 3 A FR, A, 1240313 (JUDET) 25 July 1960		1-4
see figures A WO, A, 88/07357 (KLUXER) 6 October 1988		
* Special categories of cited documents: 16 "A" document defining the general state of the art which is not considered to be of particular reference. "E" earlier document but published on or after the international filing date. "L" document which may throw doubts on priority claim(s) or which is cried to establish the publication date of another citation or other special reason (as specified). "O" document referring to an oral disclosure, use, exhibition or other means. "P" document published prior to the international filing date but later than the priority date claimed.	cited to understand the prinxention "X" document of particular relicannot be considered now involve an inventive step "Y" document of particular relicannot be considered to inventional considered considered to inventional considered co	evance: the claimed invention of or cannot be considered to sevence: the claimed invention of the considered to sevence: the claimed invention over an inventive step when the cone or more other such documing obvious to a person skilled
IV. CERTIFICATION		and Sauch Banes
Date of the Actual Completion of the International Search 12 October 1990 (12.10.90)	Date of Mailing of this Internation 30 October 1990 (
	Signature of Authorized Officer	
International Searching Authority	1 - Angulares a	

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

FR 9000285

SA 36737

This ansex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 23/10/90. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4743260	10-05-88	None	
FR-A- 2275679	16-01-76	GB-A- 1519139	26-07-78
EP-A- 0140790	08-05-85	FR-A,B 2553993 JP-A- 60111651 US-A- 4697582	18-06-85
FR-A- 1240313		None	
WO-A- 8807357	06-10-88	DE-A- 3711091 EP-A- 0316371	*2 10 00

RAPPORT DE RECHERCHE INTERNATIONALE

Demande Internationale Nº PCT/FR 90/00285 I. CLASSEMENT DE L'INVENTION (si plusieurs symboles de classification sont applicables, les indiquer tous)? Selon la classification internationale des brevets (CIS) ou à le lois selon la classification nationale et la CIS CIB⁵: A 61 F 2/44, A 61 B 17/60 II. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE Documentation minimale consumes * Système de classification Symboles de classification CIB⁵ A 61 F, A 61 B Documentation consultée autre que la documentation minimale dans le mesure † ènce a porté de tels documents font partie des domaines sur lesquels la recherche a porté f III. DOCUMENTS CONSIDERÉS COMME PERTINENTS " Identification des decuments crès. 11 èvec indication, si nécessaire, des sessages pertinents 12 Catégorie * Nº des revendications modes 18 X US, A, 4743260 (BURTON) 1-5 10 mai 1988 voir le document en entier Y 7-10 Y FR, A, 2275679 (CROCK et al.) 7-10 16 janvier 1976 voir page 4, lignes 18-35; figures 4-6 X EP, A, 0140790 (PEZE) 8 mai 1985 voir résumé; figure 3 A FR, A, 1240313 (JUDET) 25 juillet 1960 1-4 voir figures Α WO, A, 88/07357 (KLUGER) 6 octobre 1988 * Catégories spéciales de documenta citée: 11 e 7 » decument ulténeur publié pesténeurement à le date de depôt international ou à la date se prierite et n'appartenant pas à l'état de la technique portinent, mais cité pour comprendre le principe ou la théorie constituent la base de l'invention d A » document définissant l'état général de la technique, non considéré comme particulièrement pertinent « E » decument antérieur, mars publié à la date de dépôt interne-tional ou après certe date e X p decument particulièrement partinunt: l'invention revendu-quée ne pout être considères comme neuvelle au comme impliquant une activité inventire decument powent jeter un doute sur une revendication de pnorné ou cité pour déterminer la date se sublication d'une suire cratien ou peur une raison saéciale (telle su'indiquée) a Y a document particulièrement pertinent; l'invertion reven-équée ne peut être considérée comme impuellant une activité inventive lorsaue le document est assecté à un eu plusieurs autres documents se même nature, care combi-naisen étant évidente pour une personne du metier. d O a decument se référant à une divulgation orale, à un usage, à une exposition ou tous autres moyens de Po document publié avant la date de dépôt international, mais postérieurement à la date de priorité revendiquée e à 9 document qui fait partie de la même famille de brevets IV. CERTIFICATION Date à laquelle la recherche internationale a été effectivement Date d'expédition du présent rapport de propertie internationale 12 octobre 1990 -Administration chargée de la recherche internationale Signature du fonctionnaire vitorisé OFFICE EUROPEEN DES BREVETS MISS D.

ANNEXE AU RAPPORT DE RECHERCHE INTERNATIONALE RELATIF A LA DEMANDE INTERNATIONALE NO.

FR 9000285

36737

La présente ansexe indique les membres de la famille de brevets relatifs aux documents brevets cités dans le rapport de

recuerrise internacionair vise ci-acissus.

Lesdits membres sont contenus au fichier informatique de l'Office européen des brevets à la date du 23/10/90.

Les renseignements fournis sont donnes à titre indicatif et n'engagent pas la responsabilité de l'Office européen des brevets.

Document brevet cité au rapport ét recherche	Date de publicacion	Membre(s) *e la famille de brevet(s)	Date de publication
US-A- 4743260	10-05-88	Aucun	,
FR-A- 2275679	16-01-76	GB-A- 1519139	26-07-78
EP-A- 0140790	08-05-85	FR-A,B 2553993 JP-A- 60111651 US-A- 4697582	03-05-85
FR-A- 1240313		Aucun	*****
WO-A- 8807357.	06-10-88	DE-A- 3711091 EP-A- 0316371	13-10-88 24-05-89